



Maryland Department of Health and Mental Hygiene
Office of Health Care Quality – Laboratory Licensing Programs
Spring Grove Center – Bland Bryant Building
55 Wade Avenue, Catonsville, MD 21228
Phone: 410.402.8025 Fax: 410.402.8213

Instructions for Completion of State Compliance Application

*****Changes to your State laboratory license must be submitted on the Laboratory Licensing Change Form. The form can be downloaded on our website at www.dhmf.state.md.us/ohcq *****

It is important that you fill out the application completely, including signatures where required. If the application is incomplete it will delay the licensing process.

Please submit no money at this time. Once your application is reviewed for completeness and compliance with the applicable regulations, you will be issued an invoice for the application fee as well as other fees as outlined in COMAR 10.10.04.02.

Once your payment is received, the appropriate license will be issued.

If you have any questions, please call the Laboratory Licensing Division at (410) 402-8025.

*****Important*****

*****Before submitting your application, please review the checklist on the last page.*****



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Official Use Only

State of Maryland
Department of Health and Mental Hygiene
Laboratory Licensing Programs
Office of Health Care Quality



Date/Amount Paid

Invoice #

Check #

State Permit #

CLIA #

State Compliance Application

Check all that apply: ☐ General Permit: complete Schedule A ☐ Letter of Exception: complete Schedule B ☐ Initial Application ☐ Renewal Application

I. Laboratory Information

Type of Laboratory ☐ Physician Office ☐ Point of Care ☐ Independent/Reference ☐ Hospital

Laboratory Practice/ Entity Name

Contact Person Name/Phone Number

Address, City, State and Zip Code

Email Address

Mailing address if different from above

II. Director Information

Director Name

Degree

Full Time

Part Time (hours/week)

Certification by American Specialty Board (Name, Date, Number)

State Medical License Number

III. Laboratory Supervisor/Consulting Supervisor/Manager Information

Name

Degree

Full Time

Part Time (hours/week)

Certification by American Specialty Board (Name, Date, Number)

IV. Schedule A - General Permit

Chemistry <input type="checkbox"/> Routine <input type="checkbox"/> Blood Gas <input type="checkbox"/> Endocrinology <input type="checkbox"/> Toxicology: Drugs of Abuse <input type="checkbox"/> Toxicology: Therapeutic <input type="checkbox"/> Toxicology: Heavy Metals <input type="checkbox"/> Radioimmunoassay	Genetics <input type="checkbox"/> Routine <input type="checkbox"/> Molecular <input type="checkbox"/> Cytogenetics	Forensic Toxicology <input type="checkbox"/> Toxicology: Job Related	Microbiology <input type="checkbox"/> Bacteriology <input type="checkbox"/> Parasitology <input type="checkbox"/> Mycology <input type="checkbox"/> Mycobacteriology <input type="checkbox"/> Virology	Health Awareness <input type="checkbox"/> Cholesterol/HDL <input type="checkbox"/> Other Excepted Tests * * Excepted tests under Health Awareness require a General Permit.
Immunohematology <input type="checkbox"/> ABO/Rh/Non Transfusion/Transplant <input type="checkbox"/> ABO/Rh <input type="checkbox"/> Antibody Detection <input type="checkbox"/> Antibody Identification <input type="checkbox"/> Compatibility Testing	Hematology <input type="checkbox"/> Routine <input type="checkbox"/> Coagulation	Molecular Biology <input type="checkbox"/> Nucleic Acid Probes <input type="checkbox"/> PCR Amplifications <input type="checkbox"/> Recombinant Nucleic Acid Techniques	Pathology <input type="checkbox"/> Histopathology <input type="checkbox"/> Dermatopathology <input type="checkbox"/> Oral Pathology <input type="checkbox"/> Cytology-GYN <input type="checkbox"/> Cytology-Non- GYN	Immunology <input type="checkbox"/> General Immunology <input type="checkbox"/> Syphilis Serology <input type="checkbox"/> Histocompatibility

V. Schedule B - Excepted Tests *

* Note: Not all tests excepted by Maryland regulations are waived by CLIA. You can check the test categories for CLIA at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/search.cfm>

Chemistry <input type="checkbox"/> BNP <input type="checkbox"/> Dipstick Glucose <input type="checkbox"/> Dipstick Urinalysis <input type="checkbox"/> Dipstick Microalbumin & creatinine, urine <input type="checkbox"/> Fructosamine (whole blood) <input type="checkbox"/> Glucose (FDA Home Device) <input type="checkbox"/> Hemoglobin A1c (Glycohemoglobin) <input type="checkbox"/> Microscopic Urinalysis	Hematology <input type="checkbox"/> Fern Test <input type="checkbox"/> Hematocrit <input type="checkbox"/> Hemoglobin <input type="checkbox"/> Nitrazine Test <input type="checkbox"/> Semen analysis, qualitative <input type="checkbox"/> Sickle Cell Testing
Immunology <input type="checkbox"/> Bladder marker, H-related protein, qualitative <input type="checkbox"/> H.Pylori (whole blood) <input type="checkbox"/> Heterophyle AG (whole blood) <input type="checkbox"/> Mono Slide Test <input type="checkbox"/> NMP Bladder Marker, qualitative <input type="checkbox"/> Rheumatoid Factor <input type="checkbox"/> Urine Pregnancy Test	Microbiology <input type="checkbox"/> Dermatophyte Screen <input type="checkbox"/> Fecal Fat <input type="checkbox"/> Gram Stain <input type="checkbox"/> Group A Strep Screen (non-culture) <input type="checkbox"/> Influenza Antigen (nasal or throat swab) <input type="checkbox"/> KOH Preparation <input type="checkbox"/> Occult Blood <input type="checkbox"/> Occult Blood, gastric <input type="checkbox"/> Pinworm Prep <input type="checkbox"/> Urine Colony Count (no ID) <input type="checkbox"/> Wet Mount

VI. List of Instruments and Equipment Used in the Laboratory

Please list the name of kit(s) manufacturers

VII. Proficiency Testing

☐ I am not enrolled

☐ I am enrolled (complete below)

Name of Company

Discipline

VIII. Ownership Information

A. Type of Entity

☐ Sole Proprietorship ☐ Partnership ☐ Corporation ☐ Unincorporated Association

☐ Other (Specify) _____

- B. List names and addresses for individuals and the EIN for organizations having direct or indirect ownership or a controlling interest ($\geq 5\%$) in the entity. List any additional names and addresses on a separate sheet. If related individuals are listed, the relationship must be disclosed. If the disclosing entity is a corporation, list names and addresses of the Director and the EINs for the corporations on a separate sheet.

Name	Address	EIN

IX. Attestation

I certify that the information provided in this application is true and complete, understanding that any knowing and willful false statement or representation, or failure to fully and accurately disclose the requested information in this application, may be prosecuted under applicable federal or State laws, may lead to a denial, suspension or revocation of the medical laboratory license for this entity, or could result in termination of participation in State or federal reimbursement programs. I further understand that compliance with State laws may not assure compliance with federal laws.

Signature of Laboratory Director

Date

For Informational Purposes Only
Examples of Testing for Schedule A- General Permit (Do Not Circle)

Chemistry

Alkaline Phosphatase
 Amylase
 B-HCG (quantitative)
 Blood Lead
 CK-MB
 Digoxin
 Iron
 Lipase
 Phenytoin
 T4-Free
 Troponin
 TSH
 Vitamin D

Genetics

Chromosome Analysis
 FISH Studies (Neoplastic and Congenital)
 Fragile X Screen
 Gaucher Disease (*GBA*) 8 Mutations
 Tay-Sachs (*HEXA*) 7 Mutations
 Y Chromosome Deletions

Forensic Toxicology

Job Related Alcohol
 Job Related Drugs of Abuse

Microbiology

AFB Smear
 Bacterial Culture
 Blood Culture
 CSF Bacterial Antigen
 Fungus/Yeast Culture
 Ova and Parasite
 Sensitivity Testing
 Viral Culture

Hematology

APTT
 CBC
 Differential
 Fetal Hemoglobin
 Fibrinogen
 INR
 Prothrombin Time
 Reticulocyte Count
 Sedimentation Rate

Molecular Biology

Adenovirus PCR
 BD Affirm Probe Test
 Chlamydia PCR
 EBV PCR
 HCV Genotyping
 HIV Drug Resistance Genotyping
 HIV Viral Load

Pathology

Dermatopathology
 Fine Needle Aspirations
 Grossing
 Histopathology
 Oral Pathology
 Other Cytology
 Pap Smear Interpretations

Immunology

Anti-Nuclear Antibody
 Epstein Barr Antibodies
 GM1 Antibody
 Hepatitis B Surface Antibody
 Hepatitis B Surface Antigen
 Herpes Antibody
 HIV Antibody
 Lyme Antibody
 Non Transplant Related Histocompatibility

To prevent a delay in processing your application please check to make sure all of the following are included:

- ☐ Completed application with each section completely filled out
- ☐ Signature of Medical Director must match Director name in section II of application
- ☐ If the status of your CLIA certificate is changing, a completed CMS 116 form must be submitted
- ☐ Director Qualifications
 - ☐ Copy of CV, Diploma (highest degree), ECFMG (if applicable), board certification for MD or PhD (if applicable)
- ☐ Technical Supervisor Qualifications (for the discipline of HISTOLOGY)
 - ☐ Copy of American Pathology Board certification in Anatomical Pathology
 - ☐ Copy of Maryland (Board of Physicians) license to practice medicine
- ☐ Genetics Testing
 - ☐ Copy of Technical Supervisor's diploma (must be MD, DO or PhD), board certification from the American Board of Medical Genetics or 4 years of verified (not self-generated) experience in clinical genetics and CV
 - ☐ Copy of Test Menu
 - ☐ Copy of a Validation Study of one test (includes a summary and raw data)
 - ☐ Letter from Director documenting that the lab does not perform "Direct to Consumer" testing
- ☐ Certificate of Accreditation Laboratories
 - ☐ Copy of enrollment verification from the designated accrediting organization

Applicants Located in Maryland

- ☐ Completed CLIA application in agreement with State application
- ☐ Copy of Director's Maryland (Board of Physicians) license to practice medicine
- ☐ For High Complexity Laboratories: Documentation of training, education and previous experience that meets CLIA Sec. 493.1443: Standard: Laboratory Director Qualifications
- ☐ For Moderate Complexity Laboratories: Board Certification or Documentation of 20 CME from approved programs for Medical Director that meets CLIA Sec. 493.1405
- ☐ Documentation of licensure as a practitioner seeking a Letter of Exception (midwife, nurse practitioner, PA, chiropractor, podiatrist, dentist)

Applicants Located Out of State

- ☐ Copy of CLIA certificate and State Laboratory License, if applicable
- ☐ Copy of most recent survey, which includes cited deficiencies and corrective actions
- ☐ Copy of Director's State license to practice medicine from the State where the laboratory is located
- ☐ Documentation of training, education and previous experience that meets CLIA Sec. 493.1443: Standard: Laboratory Director Qualifications
- ☐ Proof of most recent participation in annual GYN cytology proficiency testing